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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,989	11/21/2003	Xuedong Song	KCX-741 (19044)	9109

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EXAMINER	
DIRAMIO, JACQUELINE A	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/718,989	SONG, XUEDONG	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) *44-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☒ Claim(s) *15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/14/04; 10/8/04;* 12/16/04; 2/22/05; 6/13/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 – 43, drawn to a method for detecting the presence or quantity of an analyte, classified in class 436, subclass 501 for example.

II. Claims 44 – 63, drawn to a lateral flow assay device, classified in class 435, subclass 7.1 for example.

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process, such as filtration or separation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Jason Johnston on September 1, 2005 a provisional election was made without traverse to prosecute the invention of Group I,

claims 1 – 43. Affirmation of this election must be made by applicant in replying to this Office action. Claims 44 – 63 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

The references submitted in the IDS forms were considered by examiner, but due to the length and number of references submitted, Applicant is advised to submit a note of relevance for any of the references with outstanding similarity to the pending application.

Claim Objections

Claim 15 is objected to because of the following informalities:

Claim 15 recites the phrase "said detection probes exposed to a quencher," which appears to be missing the word "are" between "probes" and "exposed" as recited in claims 14 and 16.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 16, 20, 22 – 38 and 41 – 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rylatt et al. (WO 97/09620) in view of Klimant (US 6,770,220).

Rylatt et al. teach a method for quantitative determination of a target analyte in a test sample, comprising a lateral flow assay device wherein a liquid permeable membrane (porous membrane) is used, wherein said membrane contains a test zone (detection zone) and at least one calibration zone(s) (see p4, lines 29-30 and p5, lines 1-20). The membrane also utilizes an analyte detection agent (detection probe) comprising a specific binding partner and an associated label (see p7, lines 25-29 in particular). The test zone (detection zone) utilizes an immobilized analyte receptor (capture reagent) that can bind with the analyte and/or analyte detection agent (detection probe) and generate a detectable signal. Therefore, the lateral flow

membrane, containing the analyte detection agent (detection probes), is contacted with the test sample; the analyte detection agent (detection probes) binds to the target analyte and flows to the test zone (detection zone) wherein it binds to an immobilized analyte receptor, and generates a signal, which is detected and measured, thus providing the amount of analyte in the test sample, which is proportional to the intensity of the signal at the test zone (detection signal) (see p18-20 in particular).

However, Rylatt et al. fail to teach that the label associated with the analyte detection agent (detection probe) is a phosphorescent label encapsulated within a matrix.

Klimant teaches of the production and use of luminescent microparticles wherein phosphorescent labels are incorporated (encapsulated) within solid particles for use as internal standards for referencing phosphorescence signals or as markers for labeling and detecting biomolecules (see column 1, lines 1-9). Luminescence measurements using phosphorescence signals is a very common method in biological and chemical analysis dues to its high sensitivity and versatility (see column 1, lines 30-35). The incorporation of the phosphorescence labels within matrices allows for elimination or great reduction in phosphorescence signal quenching by interfering oxygen that is common during luminescence measurement (see column 1, lines 17-23).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine with the assay method of Rylatt et al. the use of a phosphorescent label encapsulated within a matrix as taught by Klimant because Klimant teaches the benefit of luminescence measurements for biological and chemical

analysis due to its high sensitivity and versatility as well as the benefit of incorporation of phosphorescence labels within matrices in order to eliminate or greatly reduce phosphorescence signal quenching by interfering oxygen that is common during luminescence measurement.

With respect to Applicant's claims 2 – 5 and 8, as well as claims 29 and 32, Klimant teaches that the phosphorescent label is a metal/ligand complex, particularly comprised of transition metals such as ruthenium, osmium, iridium, rhenium, platinum, or palladium, and also containing complex ligands, such as **bipyridine**, bipyrazine, phenanthroline, terpyridil or derivatives thereof (see column 3, lines 14-21).

With respect to Applicant's claims 6 and 7, as well as claims 30 and 31, Klimant teaches the phosphorescent label can further comprise a porphyrin ligand or porphyrin complex with platinum(II) or palladium(II), which anticipates Applicant's claims 7 and 31 because the porphyin complexes encompass the derivatives and combinations thereof and are being utilized for the same purpose (see column 3, lines 25-31).

With respect to Applicant's claims 9 and 33, Klimant teaches the matrix incorporating the phosphorescent label comprises polymer particles (see column 4, lines 11-19).

With respect to Applicant's claims 10 – 12 and 34, Klimant teaches the size of the luminescent particles in the range of 20 µm to 10 µm, particularly from 50 nm to 1 µm (see column 3, lines 37-39).

With respect to Applicant's claims 13 and 35, Klimant teaches the matrix incorporating the phosphorescent label protects the label from quenching (see column 1, lines 17-23).

With respect to Applicant's claims 14 – 16 and 36 – 38, Klimant teaches the matrix incorporating the phosphorescent label protects the label from quenching, enabling the luminescence lifetime (detection signal) to be only 20%, at most 15% and preferably at most 10% shorter than in an O_2 free environment, which anticipates Applicant's claims 14 – 16 and 36 – 38 (see column 3, lines 5-13).

With respect to Applicant's claim 20, Rylatt et al. teach that the analyte receptor (capture reagent) in the test zone is a specific binding partner for the analyte, which includes the specific binding pairs of antigens and antibodies, lectins and carbohydrates, peptides, proteins, avidin, streptavidin, or biotin (see p6, lines 4-14 and p9, lines 15-19).

With respect to Applicant's claims 22 and 23, as well as claims 41 and 42, Rylatt et al. teach of a calibration zone wherein a calibration agent receptor is immobilized to bind to the specific binding partner found on the analyte detection agent (detection probe) or calibration agent (calibration probe) and further, the binding of the agent to the calibration zone produces a calibration signal that is used to calibrate the signal produced in the test zone (detection signal) (see p5, lines 10-20 and p9, lines 13-19 in particular).

With respect to Applicant's claims 24 and 25, as well as claim 43, Rylatt et al. teach that the analyte detection agent (detection probe) comprises a specific binding

partner and an associated label, wherein the specific binding partner is selected from the group consisting of antigens, antibodies, peptides, proteins, lectins, enzymes, etc. (see p6, lines 7-14 and p7, lines 28-29 in particular).

With respect to Applicant's claims 26 and 27, Rylatt et al. teach that the assay device can be either used in a sandwich-type or competitive format (see examples 1-3).

With respect to Applicant's claim 28, the method recited in this claim is similarly anticipated by the combination of the Rylatt et al. and Klimant references, which has been discussed above.

Claims 17 – 19, 21, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rylatt et al. (WO 97/09620) in view of Klimant (US 6,770,220) as applied to claims 1 and 28 above, and further in view of O'Riordan et al. ("Performance Evaluation of the Phosphorescent Porphyin Label: Solid-Phase Immunoassay of α-Fetoprotein," *Anal. Chem.* 74 (2002) 5845-5850).

Both Rylatt et al. and Klimant fail to teach that the phosphorescent label has an emission lifetime greater than about 1, 10, or 100 to about 1000 microseconds or that the phosphorescent metal complex is excited with a pulsed excitation source and the emitted signal is measured by a time-gated detector.

O'Riordan et al. teach a solid-phase immunoassay utilizing phosphorescent porphyin labels, particularly platinum(II)-coproporphyrin-I, which display high quantum yields, long phosphorescent lifetimes in the 10-1000 microsecond range and intense

absorption bands, allowing for high sensitivity during assays (see p5845, paragraph 2). The measurement of the phosphorescent labels was accomplished by excitation with a 1 – 50-μs square pulse, a 50-μs delay time, 100-μs gate time, and a 1-s integration time, which gave the highest signal/noise ratio and therefore, used as the standard parameters for signal emission and detection (see p5848, *Evaluation of Instrument Performance*).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine with the assay method of Rylatt et al. and the phosphorescent label encapsulated within a matrix as taught by Klimant the phosphorescent porphyin labels as taught by O'Riordan et al. because O'Riordan et al. teach the benefit of these labels because of their high quantum yields, long phosphorescent lifetimes in the 10-1000 microsecond range and intense absorption bands, which allow for high sensitivity during assays. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine with the assay method of Rylatt et al. and the phosphorescent label encapsulated within a matrix as taught by Klimant the excitation and signal detection parameters taught by O'Riordan et al. because O'Riordan et al. teach the benefit of this type of phosphorescent excitation and signal detection because of its high signal/noise ratio.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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09/14/05